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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gray et al.
Title: SURGICAL DEVICE WITH
MALLEABLE SHAFT
Appl. No.: 09/432,523
Filing Date: 3 November 1999
Examiner: D. Isabella
Art Unit: 3731

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RESPONSE TO OFFICE ACTION REGARDING APPEAL BRIEF

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In response to the Office Action mailed 28 November 2003, Applicant encloses three (3) copies of the Appeal Brief.

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Respectfully submitted,

Date 11 December 2003
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112-30-03
Atty. Dkt. No. 050251/0131

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

#24/Brief

Applicant: Gray et al.

Title: SURGICAL DEVICE WITH
MALLEABLE SHAFT

Appl. No.: 09/432,523

Filing Date: 3 November 1999

Examiner: David J. Isabella

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APPEAL BRIEF

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Assistant Commissioner for Patents
Washington, D.C. 20231

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I. STATUS OF CLAIMS

Claims 37-39, 41 and 42 are pending. Claims 37-39, 41 and 42 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,871,496 to *Ginn et al.* or U.S. Patent No. 5,749,889 to *Bacich et al.* Claims 37-39, 41 and 42 stand rejected under 35 U.S.C. § 103 as obvious in view of U.S. Patent No. 3,915,169 to *McGuire* in further view U.S. Patent No. 5,871,496 to *Ginn et al.* or U.S. Patent No. 5,749,889 to *Bacich et al.* Claims 37-39, 41 and 42 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,782,834 to *Lucey et al.* ("*Lucey*"). The claims in their current condition are attached hereto in the Appendix.

II. STATUS OF AMENDMENTS

No amendments are outstanding.

III. SUMMARY OF THE INVENTION

The present invention provides a surgical device having a tissue engaging portion, a shaft member, and a handle assembly. The tissue engaging portion includes first and second opposed jaws for grasping, securing, and occluding body tissue and conduits. The shaft member is

operatively coupled to the tissue engaging portion and is malleable. The handle assembly is operatively coupled to both the shaft member and to the tissue engaging portion. The shaft member of the present invention allows the surgeon to bend and adjust the shape of the surgical device to minimize its intrusion and to allow for proper positioning in predetermined body locations.

IV. ISSUES

Whether the inventions as claimed in claims 37-39, 41 and 42 are anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 5,871,496 to *Ginn et al.* or U.S. Patent No. 5,749,889 to *Bacich et al.* Whether the inventions as claimed in claims 37-39, 41 and 42 would have been obvious to a person of ordinary skill in the art, at the time the invention was made, under 35 U.S.C. § 103 in view of U.S. Patent No. 3,915,169 to *McGuire* in further view of U.S. Patent No. 5,871,496 to *Ginn et al.* or U.S. Patent No. 5,749,889 to *Bacich et al.* Whether the inventions as claimed in claims 37-39, 41 and 42 are anticipated under 35 U.S.C. § 102(c) by U.S. Patent No. 5,782,834 to *Lucey et al.* ("*Lucey*"). The claims in their current condition are attached hereto in the Appendix.

V. GROUPING OF CLAIMS

Claims 37-39, 41 and 42 will be discussed together.

VI. ARGUMENT

A. Background.

Claims 37-39, 41 and 42 are pending.

The present application was filed on 3 November 1999 as a continuation of issued U.S. Patent No. 6,139,563, with claims 37-42. In the first Office Action mailed on 9 March 2000, claims 37, 40 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,483,562 to *Schoolman* ("*Schoolman*") while claims 37-39, 41 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,945,920 to *Clossick* ("*Clossick*"). In response, claim 37 was amended and claims 43-45 were added.

In an Office Action mailed 12 March 2001, claim 43 was rejected under 35 U.S.C. § 102(b) as anticipated by *Schoolman* while claims 37-39, 41 and 42 [sic] were rejected under 35 U.S.C. § 102(b) as anticipated by *Clossick*. Claims 41 and 42 [sic] were indicated as containing allowable subject matter but rejected as depending on a rejected base claim. No comments were made on claims 44 and 45. In response, claims 37 and 43 were amended, claim 44 was cancelled, and claims 46-54 were added.

In response, on 20 March 2002 a Restriction Requirement was issued. The Restriction Requirement set forth four species, including listing previously examined claims 37 and 43 as separate species. In response, pending claims 37-39, 41 and 42 were elected.

Next, in an Office Action mailed 5 July 2002, claims 37, 38, 39, 41 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,318,528 to *Heaven et al.*, U.S. Patent No. 5,336,221 to *Anderson*, *Clossick* or U.S. Patent No. 5,254,130 to *Poncet et al.* In response, these rejections were traversed.

Next, an Office Action mailed on 29 May 2003 rejected claims 37-39, 41 and 42 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,871,496 to *Ginn et al.* or U.S. Patent No. 5,749,889 to *Bacich et al.*; rejected claims 37-39, 41 and 42 under 35 U.S.C. § 103 as obvious in view of U.S. Patent No. 3,915,169 to *McGuire* in further view of U.S. Patent No. 5,749,889 to *Bacich et al.* or U.S. Patent No. 5,871,496 to *Ginn et al.*; and rejected claims 37-39, 41 and 42 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,782,834 to *Lucey et al.* Again, these rejections were traversed.

In the Final Office Action mailed 29 May 2003, the Office Action repeated the rejections based on U.S. Patent No. 5,871,496 to *Ginn et al.*; U.S. Patent No. 5,749,889 to *Bacich et al.*; U.S. Patent No. 3,915,169 to *McGuire*; and U.S. Patent No. 5,782,834 to *Lucey et al.* Thus, in five Office Actions three different sets of prior art comprising nine different patents have been applied and with previously examined claims subsequently separated out as different species. Review of the most recent set of rejections demonstrates that these recently applied references fall into the same scrap pile as U.S. Patent No. 4,483,562 to *Schoolman*; U.S. Patent No. 4,945,920 to *Clossick*; U.S. Patent No. 5,318,528 to *Heaven et al.*, U.S. Patent No. 5,336,221 to *Anderson*, and U.S. Patent No. 5,254,130 to *Poncet et al.*

B. Discussion

Independent claim 37 claims a surgical clamp comprising five elements:

- “an elongate, one-piece, malleable hollow shaft including a distal end and a proximal end;
- “a tissue clamp assembly including first and second movable opposable jaws mounted at the distal end adopted to grasp, secure and occlude body tissue and conduits;
- “a handle assembly including first and second movable arms mounted at the proximal end; and
- “an elongate actuator disposed within the hollow shaft including a first end operatively connected to the tissue clamp assembly and a second end operatively connected to the handle assembly

“such that when the handle arms are moved from a first relative position to a second relative position, the first and second jaws of the tissue clamp assembly are moved between an open spaced apart position and a closed tissue gripping position or vice versa.”

Initially, claims 37-39, 41 and 42 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,871,496 to *Ginn et al.* or U.S. Patent No. 5,749,889 to *Bacich et al.* U.S. Patent No. 5,871,496 to *Ginn et al.* (“*Ginn*”) describes a surgical instrument specifically designed for a procedure of detaching an internal mammary artery (IMA) and the like, from the connecting tissues and side branch vessels which surround the artery in its native location. This detaching procedure is preliminary to the performing of a coronary artery bypass grafting procedure. An elongated slender rod includes a handle at its proximal end and an artery engaging loop, arc, fork configuration, or hook at its distal working end. The surgical instrument of *Ginn* “captures and gently stabilizes IMA” (column 8 ,line 41) so that a separate instrument such as a surgical scissors 22 (figure 3) or a electro-surgical knife 148 (figure 13) can do its job.

Thus, it is not seen where the introducer of *Ginn* describes, teaches or discloses the present invention. “A prior art reference *anticipates* a claim *only* if the reference discloses, either expressly or inherently, every limitation of the claim.” *Rowe v. Dror*, 112 F.3d 473, 42 U.S.P.Q.2d 1550, 1553 (Fed. Cir. 1997) (emphasis added). Where is the handle assembly with movable arms? The Office Actions points to a sixth embodiment seen in Figure 14 and “column 8, lines 53+” of *Ginn* in attempting to justify its rejection. Figure 14 depicts a three prong fork 162 in which the middle finger 166 articulates. This middle finger is connected to the fork by a

pivot bearing 168 and toggles either right or left by pulling on a right or left cable to engage the outer stationary finger 164. However, *Ginn* in no way describes, teaches or discloses how these "cables" could be employed with a malleable shaft, how the cables would be actuated or what the handle of the Figure 14 embodiment would look like. Indeed, the handle assembly 14 of the previous five embodiments in no way resembles a handle assembly with movable arms. In fact, *Ginn teaches away* from the present invention as in Figure 22 it shows a separate scissors assembly 22 which has a first and second movable opposable jaws being used *with* the device of *Ginn* 12, thus demonstrating that the applicant was aware of first and second movable opposable jaws assembly but did not include this within his device.

U.S. Patent No. 5,749,889 to *Bacich et al.* describes a surgical introducer for endoscopic surgeries comprising surgical cutting procedures. As seen in Figures 1 and 2, the device includes a distal insertion portion 102 for insertion into a patient and a proximal housing 104. The proximal housing includes a main or endoscopic port 114 and a secondary or instrument port 116. The endoscopic port is connected to a main or endoscopic channel 122. The instrument port is connected to a guide channel 118 mounted and formed on an exterior surface 120 of the endoscopic channel 122.

The endoscopic channel and the guide channel are very different. Referring to Figure 3 and 4 of the patent, cross-sectional views of the endoscopic channel and the guide channel are seen. The endoscopic channel is made up of an inner tube 132 which defines a lumen 130. The inner tube is in turn surrounded by a larger diameter split tube or sheath 134. A split in the sheath 134 defines a slit or longitudinal opening 136. Sandwiched between the inner tube and the outer split sheath is a membrane 140 which forms the guide channel. Figure 3 shows the membrane lying draped on the endoscopic channel while Figure 4 shows the membrane with an instrument extending therethrough.

Thus, it is not seen where the introducer of *Bacich et al* describes, teaches or discloses the present invention. Where is the malleable shaft? Where is the tissue clamp assembly? Where is the handle assembly with movable arms? The Office Action broadly points to "column 3, lines 27+, column 8, lines 27+, column 10 and [sic] lines 1+" of *Bacich* in attempting to justify its

rejection. However, nowhere in this 147 lines of *Bacich* is the malleable shaft, the tissue clamp assembly or the handle assembly with movable arms described, taught or disclosed.

Apparently recognizing the deficiencies of *Ginn* and *Bacich*, the Office Action's fall back position is to attempt to combine these references with yet another reference under 35 U.S.C. § 103: U.S. Patent No. 3,915,169 to *McGuire* ("*McGuire*"). *McGuire* describes a surgical knife for removing meniscus from human knee joints. The knife has a malleable shaft portion so the surgeon can direct the knife to the desired path of incision. "[The] blade is preferably formed of spring steel so that it can flex and thus form a hinge joint in the shank." (Column 3, lines 48-50). A wire 8 extends between the blade 20 and a trigger 2 on the handle portion 1 of the knife. Thus, the angle of the blade can be varied by the surgeon between the positions seen, for example, in figure 2 and figure 5.

Thus, it is not seen where the knife of *McGuire* salvages the deficiencies of *Ginn* or *Bacich*. Where is the tissue clamp assembly? Where is the handle assembly with movable arms? Would the combined device of *McGuire* and *Ginn et al.* "capture and gently stabilize" as taught by *Ginn* or cut the tissue as taught by *McGuire*? How would using the introducer of *Bacich* with the knife of *McGuire* describe, teach or disclose the present invention? See e.g. *Rowe v. Dror*, 42 U.S.P.Q.2d at 1555 ("about the most that can be said for the [prior art] patent is that it does not explicitly describe anything inconsistent with the [claimed invention].")

In attempting to justify the rejection of the claims based on the combination of *Ginn* or *Bacich* with *McGuire*, the Office Action exposes the faulty reasoning behind all of these rejections. The Office Action boldly concludes that "*Ginn et al.* and *Bacich et al.* teaches the equivalence between surgical tools such as knives, clamps, forceps, etc. all used in combination with malleable shafts." *Ginn* and *Bacich* teach nothing of the sort. The Office Action goes on to argue "examiner rejection merely replaces one surgical tool for another since *Ginn* and *Bacich* teaches the doctrine of equivalence [sic] between the various surgical tools including knives, clamps, forceps." This attempted justification for the hindsight recreation of the invention is improper.

As this Board knows, the Supreme Court has expressly prohibited the use of hindsight to "read into the prior art the teachings of the invention in issue." *Graham v. John Deere Co.*, 383

U.S. 1, 36, 148 USPQ 459, 474 (1966). Any rejection must avoid the "hindsight gained from knowing that the inventor[s] choose to combine the particular things in this particular way." *Uniroyal Inc. v. Ruddin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). In *In re Rijckaert*, 9 F.3d 1531, 1532, (Fed. Cir. 1993), the Federal Circuit outlined the burden on the PTO as follows:

"In rejecting claims under 35 U.S.C. 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.* "A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell*, 991 F.2d 781, 782, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 531 F.2d 1048, 1051, 189 U.S.P.Q. 143, 147 (CCPA 1976)). If the examiner fails to establish a *prima facie* case, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988)."

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the prior art reference or to combine reference teachings. Second, there must be a reasonable expectation of success of achieving the desired goals. Finally, the prior art references when combined must teach ***all the claim limitations***. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The Federal Circuit stated that the Patent Office can satisfy its burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art, would lead that individual to combine the relevant teachings of the references. *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). One cannot use hindsight reconstruction to pick and choose among disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. Here, this standard has not been met.

Finally, claims 37-39, 41 and 42 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,782,834 to *Lucey et al.* ("*Lucey*"). *Lucey* describes a surgical instrument in

which a surgical tool 12 is carried distally of a bend region 20 in an outer stationary tube 14. A mounting assembly 22 transmits proximally applied forces through the bend region to both operate the surgical tool and selectively change the rotational orientation of the surgical tool with respect to the stationary member. The mounting assembly includes a pair of coaxial tubes 32, 34 disposed within outer stationary tube 14. Intermediate tube 32 is disposed between outer stationary tube 14 and innermost tube 34, and carries the surgical tool:

“The portion of the tubes 32, 34 that lie within the bend region 20 [of the outer stationary tube] are flexible to allow tubes 32, 34 to both accommodate themselves to the curvature imposed by bend region 20 without becoming unduly stressed, and to transmit the applied rotational and axial forces through (i.e., beyond) bend region to surgical tool.”

(Column 5, lines 48-53).

The Office Action argues that “Claim 37 utilizes a [sic] open ended transitional phrase ‘comprising’ which does not preclude more than one element in the overall device”, pointing to “[t]he segment 40 of Lucey, et al as a substructure of the total device clearly anticipates the claim [37] as broadly worded.” This reference refers to the “flexible region 40 disposed slightly proximally of distal end 42” of intermediate tube 32 seen in figure 3 of *Lucey*. (Column 5, lines 54-56). This flexible region 40 is formed by a series of circumferential slots 44 formed in the walls 48 of tube 32 flexible region 40 to provide uniform flexibility and avoid any substantial deviations in flexibility as tube 32 is rotated within stationary tube 14.

Thus, it is not seen where the flexible, inner tube of Lucey describes, teaches or discloses the present invention. Where is the malleable shaft? Where is the tissue clamp assembly? Where is the handle assembly with movable arms?

It is respectfully submitted that all of the claims recite patentable subject matter and are in condition for allowance. Accordingly, favorable consideration and allowance of the application is respectfully requested.

VII. CONCLUSION

Claims 37-39, 41 and 42 are not anticipated by U.S. Patent No. 5,871,496 to *Ginn et al.* or U.S. Patent No. 5,749,889 to *Bacich et al.* Nor does the disclosure of U.S. Patent No. 3,915,169 to *McGuire* salvage *Ginn* or *Bacich*: claims 37-39, 41 and 42 would not have been

obvious to a person of ordinary skill in the art, at the time the invention was made. Finally, claims 37-39, 41 and 42 are not anticipated by U.S. Patent No. 5,782,834 to *Lucey et al.* Accordingly, favorable consideration and allowance of the application is respectfully requested.

Dated: 29 Aug 2003

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APPENDIX

37. A surgical clamp comprising:

an elongate, one-piece, malleable hollow shaft including a distal end and a proximal end;

a tissue clamp assembly including first and second movable opposable jaws mounted at the distal end adapted to grasp, secure and occlude body tissue and conduits;

a handle assembly including first and second movable arms mounted at the proximal end; and

an elongate actuator disposed within the hollow shaft including a first end operatively connected to the tissue clamp assembly and a second end operatively connected to the handle assembly such that when the handle arms are moved from a first relative position to a second relative position, the first and second jaws of the tissue clamp assembly are moved between an open spaced apart position and a closed tissue gripping position or vice versa.

38. A malleable surgical clamp as defined in claim 37, wherein the malleable hollow shaft comprises soft metal tubing.

39. A malleable surgical clamp as defined in claim 37, wherein the malleable hollow shaft comprises wound metal tubing.

41. A malleable surgical clamp as defined in claim 37, wherein the malleable hollow shaft comprises a multi-lumen thermoplastic polymer tubing, the elongate actuator being disposed in a first lumen of the multi-lumen tubing and the hollow shaft further including a malleable rod disposed in a second lumen of the multi-lumen tubing.

42. A malleable surgical clamp as defined in claim 37, wherein the malleable hollow shaft is capable of being placed in different curvatures.